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| 09/680,465 | 10/06/2000 | Daniel A. Japuntich | 48317USA1I.028 | 8753 |

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| EXAMINER |
|---|
| LEWIS, AARON J |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3743 | |

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|---|---|---|
| | 09/680,465 | JAPUNTICH ET AL. |
| | Examiner | Art Unit |
| | AARON J. LEWIS | 3743 |

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02/21/2006 (RCE)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *33,35-57,60-63 and 66-83* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33,35-57,60-63 and 66-83* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

## DETAILED ACTION

### *Continued Examination Under 37 CFR 1.114*

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under *Ex Parte Quayle*, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 02/21/2006 has been entered.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 33,35-46,48-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. ('516) in view of Soderberg (EP 0 252 890 A1), Braun ('362) and Cover ('183).

As to claim 33, Simpson et al. disclose a filtering (page 1, lines 108-113) face mask (1,2) that comprises: a mask body (1,2) that is adapted to fit over the nose and mouth of a wearer (fig.1); and an exhalation valve (12) that is positioned on the mask body substantially opposite to a wearer's mouth, the exhalation valve comprising: a valve seat that comprises: a seal surface (page 2, lines 37-50 and #19) and an orifice (16)

that is circumscribed by the seal surface; cross members (surfaces between orifices 16) that extend across the orifice to create a plurality of openings within the orifice; and a single flexible flap (15) that has a fixed portion (page 2, lines 46-50) and only one free portion and first and second opposing ends (page 2, lines 42-50), the first end of the single flexible flap being associated with the fixed portion of the flap so as to remain at rest during an exhalation, and the second end being associated with only the free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person (fig.1), wherein the flexible flap is positioned on the valve seat such that the flap is pressed towards the seal surface in an abutting relationship therewith when fluid is not passing through the orifice (page 2, lines 41-50).

To the extent, if any, that the flap of Simpson et al. may not be pressed towards the seal surface in an abutting relationship therewith when fluid is not passing through the orifice resort is had to Soderberg (page 4, lines 17-23), in a face mask having an exhalation valve that is pressed towards the valve seal surface in an abutting relationship therewith, when fluid is not passing through the orifice for the purpose of ensuring and maintaining a seal between the exhalation valve and the valve seat.

It would have been obvious to modify the exhalation valve of Simpson et al. to be pressed towards the valve seat in an abutting relationship therewith when fluid is not passing through the orifice because it would have ensured and maintained a seal between the valve flap and seat as taught by Soderberg.

To the extent, if any, that Simpson et al. may not disclose cross members that extend across the orifice to create a plurality of openings within the orifice, resort is had to Braun which teaches cross members (19,20) that extend across the orifice to create a plurality of openings (col.4, lines 19-22) within the orifice for the purpose of stabilizing the seal ridge and preventing the valve flap from inverting into the orifice under reverse flow (col.4, lines 32-35).

It would have been obvious to modify the orifice of Simpson et al. to include cross members extending across the orifice because it would have provided a stabilizer for the seal ridge and prevented the valve flap from inverting into the orifice under reverse flow as taught by Braun.

The difference between Simpson et al. and claim 33 is the flexible flap when secured to the valve seat at its fixed portion has a curved profile when viewed from a side elevation.

Cover (page 2, col.1, lines 3-6, lines 15-17, lines 22-33, lines 48-51) teaches an exhalation valve flap (23) when secured to the valve seat (17) at its fixed portion has a curved profile when viewed from a side elevation (figs.1,2,4) for the purpose of improving the closing action of the valve flap, improving the retention of the valve flap in effective registration with the apertures of the valve seat and causing the valve flap to function more efficiently.

It would have been obvious to modify the shape of the valve seat of Simpson et al. to have a curved profile when viewed from a side elevation because it would have improved the closing action of the valve flap, improved the retention of the valve flap in

effective registration with the apertures of the valve seat and caused the valve flap to function more efficiently as taught by Cover.

As to claims 35-36, the valves (figs.2 and 3) of Simpson et al. (page 2, lines 37-65) are disclosed as being made of plastic and/or rubber material. It would have been obvious to fabricate the valves by any well known technique which is known to be employed in the fabrication of plastics and rubber including the technique of injection molding. Further, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Inasmuch as injection molding is a widely employed technique in the fabrication of plastic and rubber materials, it would have been obvious to make the valve of Simpson et al. from a variety of well known techniques including injection molding.

As to claim 37, Simpson et al. as modified by Soderberg and Cover teach the flexible flap being pressed towards the seal surface such that there is a substantially uniform seal when the valve is in a closed position (page 2, lines 39-42). The seal (figs.2 and 3) of Simpson et al. are illustrated as being substantially uniform and since the flexible flap (15) of Simpson et al. is disclosed of being made from plastic and since known physical characteristics of plastics include flexibility and resiliency, the flap (15) of Simpson et al.

being made from plastic is fully capable of providing the recited function of "...capable of allowing the flap to display a bias towards the seal surface.".

As to claim 38, the flexible flap (15) of Simpson et al. is disclosed as being made of flexible plastic (i.e. a known elastomeric material) and as such is fully capable of performing the recited function of resisting permanent set and creep.

As to claims 39 and 42, the flexible flaps (15,18) of Simpson et al. is disclosed as being made of plastic and/or rubber for example (page 2, lines 39 and line 53). It would have been obvious to make the flexible flap from any well known flexible material including an elastomeric rubber such a polyisoprene as mere substitution of one well known flexible material for another and because elastomeric rubber is a well known material from which to make valve flaps.

As to claims 40 and 41, the degree of a seal between the valve flap and valve seat sealing surface of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal including one meeting the standards as set forth in 30 C.F.R. 11.183-2, July 01, 1991. Further, it stands to reason that one oridinary skill in the art would strive to make a face mask in accordance with at least minimum current government standards of operation including one having a valve flap having a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade.

As to claims 43-46,48,49, the particular dimensions, the particular material including the hardness of the material of the flexible flap (15,14) of Simpson et al. can be arrived

at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency. One of ordinary skill would have recognized that the particular dimensions and the particular material including hardness of the material would have been dependent upon the airflow requirements of a group of wearers, that is, an adult would require a mask and valve of a size and material that is capable of handling respiratory airflows typical of adults whereas a child or an adult with a compromised respiratory system would require a mask and valve of a size and material that is capable of handling lesser respiratory airflows.

As to claim 50, while Simpson et al. is silent as to the relative surface areas of the fixed and free portions of flap (15), it is submitted that the particular relative amounts of the fixed and free portions can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular relative amounts including 10-25% fixed and 75-90% free.

As to claim 51, the flange against which the valve flap is secured in Simpson et al. (fig.2) is illustrated as being the same 360 degrees around the valve seat.

As to claim 52, given the downward orientation of the mask body (1,2) of Simpson et al. fig.1 and given that any exhaled air must pass outward between the valve flap (15,14) and the body the of mask, it stands to reason that exhaled air will follow a path which is generally parallel to the upper surface of the body of the mask which itself is downwardly oriented as illustrated in fig.1. Therefore, exhaled air is deflected downwardly during use of the mask of Simpson et al..

As to claim 53, Simpson et al. (page 1, lines 116-123) disclose the mask body is cup-shaped and comprises at least one shaping layer for providing structure to the mask, and a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

As to claim 54-56, while Simpson et al. do not address the particular volume of a wearer's exhalation exiting the exhalation valve (12), it is submitted that since the exhalation valve (12) is expressly disclosed as opening in response to a wearer's exhalation, the valve of Simpson et al. is fully capable of providing the recited function inasmuch as it would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve 12 of Simpson et al..

As to claim 57, since the mask body (1,2) of Simpson et al. is angled downwardly when positioned on wearer's face, the valve (12) on mask body (1,2) of Simpson et al. is positioned substantially opposite a wearer's mouth (fig.1). The valve flap (15) of Simpson et al. is mounted on the valve seat (fig.2) in cantilever fashion.

4. Claims 60-63,83 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of Soderberg (EP 0 252 890), Braun ('362) and Cover ('183) as applied to claim 33,35-46,48-57 above, and further in view of Warbasse ('706).

As to claim 60, Simpson et al. as modified by Soderberg, Braun and Cover as discussed above with respect to claim 33 also teach cross members (#25 and col.4, lines 25-26 of Braun) that are disposed within the opening of the valve cover for the purpose of protecting the valve flap against debris.

The differences between Simpson et al. and claim 60 are an opening that is disposed directly in the path of fluid flow when a free portion of the flexible flap is lifted from the seal surface during an exhalation; a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end.

Warbasse teaches a valve cover (11) having a fluid impermeable ceiling that increases in height in the direction of the flexible flap from the first end to the second end for the purposes of protecting the valve flap (12), controlling the extent of movement of the valve flap, and controlling the direction of fluid flow exiting the mask via the valve.

It would have been obvious to further modify the valve (fig.2) of Simpson et al. to provide a valve cover because it would have provided a means for protecting the valve flap (12), controlling the extent of movement of the valve flap, and controlling the direction of fluid flow exiting the mask via the valve as taught by Warbasse.

As to claim 61, Warbasse teach a valve cover (11 of fig.2) having an opening in the valve cover which is approximately parallel to the path traced by the second end of the flexible flap during its opening and closing.

As to claim 62, Simpson et al. as further modified by Warbasse teach a cover which directs exhaled downwards when the mask is worn by a person.

As to claim 63, the cover (#11 of figs.2 and 3) of Warbasse shows fluid impermeable sidewalls.

As to claim 83, the opening in the cover of Warbasse (figs.2 and 3) is illustrated as being at least the size of the orifice in the valve seat.

5. Claims 66-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. ('516) in view of Soderberg (EP 0 252 890) and Cover ('183).

To the extent, if any, that the flap of Simpson et al. may not be pressed towards the seal surface in an abutting relationship therewith when fluid is not passing through the orifice resort is had to Soderberg (page 4, lines 17-23), in a face mask having an exhalation valve that is pressed towards the valve seal surface in an abutting relationship therewith, when fluid is not passing through the orifice for the purpose of ensuring and maintaining a seal between the exhalation valve and the valve seat.

It would have been obvious to modify the exhalation valve of Simpson et al. to be pressed towards the valve seat in an abutting relationship therewith when fluid is not passing through the orifice because it would have ensured and maintained a seal between the valve flap and seat as taught by Soderberg.

The difference between Simpson et al. and claim 66 is the flexible flap when secured to the valve seat at its fixed portion has a curved profile when viewed from a side elevation.

Cover (page 2, col.1, lines 3-6, lines 15-17, lines 22-33, lines 48-51) teaches an exhalation valve flap (23) when secured to the valve seat (17) at its fixed portion has a curved profile when viewed from a side elevation (figs.1,2,4) for the purpose of improving the closing action of the valve flap, improving the retention of the valve flap in effective registration with the apertures of the valve seat and causing the valve flap to function more efficiently.

It would have been obvious to modify the shape of the valve seat of Simpson et al. to have a curved profile when viewed from a side elevation because it would have improved the closing action of the valve flap, improved the retention of the valve flap in effective registration with the apertures of the valve seat and caused the valve flap to function more efficiently as taught by Cover.

As to claim 67, Simpson et al. as modified by Soderberg and Cover as discussed above with respect to claim 66 also teach a non-centrally disposed stationary segment and a only one free portion which are analogous to the abovementioned fixed portion and free portion of claim 66.

As to claim 68, the seal surface of each of Simpson et al. as modified by Soderberg and Cover is substantially uniformly smooth to insure that a good seal occurs between the single flexible flap and the seal surface, and wherein the flexible flap is made from a material that is capable of allowing the flap to display a bias towards the seal surface (Cover, page 2, col.1, lines 3-6, lines 15-17, lines 22-33, lines 48-51).

As to claim 69, the flexible flap (15) of Simpson et al. is disclosed as being made of flexible plastic and as such is fully capable of performing the recited function of resisting permanent set and creep.

As to claim 70, the degree of a seal between the valve flap and valve seat sealing surface of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular degree of seal including one meeting the standards as set forth in 30 C.F.R. 11.183-2, July 01, 1991. Further, it stands to reason that one oridinary skill in the art would strive to make a face

mask in accordance with at least minimum current government standards of operation including one having a valve flap having a stress relaxation sufficient to keep the flexible flap in an abutting relationship to the seal surface under any static orientation for 24 hrs. at 70 degrees centigrade.

As to claims 71-74, the flexible flaps (15,18) of Simpson et al. is disclosed as being made of plastic and/or rubber for example (page 2, lines 39 and line 53). It would have been obvious to make the flexible flap from any well known flexible material including an elastomeric rubber such a polyisoprene as mere substitution of one well known flexible material for another and because elastomeric rubber is a well known material from which to make valve flaps and the particular dimensions, the particular material including the hardness of the material of the flexible flap (15,14) of Simpson et al. can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular dimensions nor in any particular constituency. For example, the relative dimensions of the flap would depend upon the overall size of the mask (adult or child size) as well as on the desired volume of airflow intended to pass through the valve opening. The particular material and degree of hardness employed for the valve flap would depend how well the valve and seat material mated together to form a seal.

As to claim 75, given the downward orientation of the mask body (1,2) of Simpson et al. fig.1 and given that any exhaled air must pass outward between the valve flap (15,14) and the body the of mask, it stands to reason that exhaled air will follow a path which is generally parallel to the upper surface of the body of the mask which itself is

downwardly oriented as illustrated in fig.1. Therefore, exhaled air is deflected downwardly during use of the mask of Simpson et al..

As to claim 76, Simpson et al. (page 1, lines 116-123) disclose the mask body is cup-shaped and comprises at least one shaping layer for providing structure to the mask, and a filtration layer, the at least one shaping layer being located outside of the filtration layer on the mask body.

As to claims 77 and 78, while Simpson et al. do not address the particular volume of a wearer's exhalation exiting the exhalation valve (12), it is submitted that since the exhalation valve (12) is expressly disclosed as opening in response to a wearer's exhalation, the valve of Simpson et al. is fully capable of providing the recited function inasmuch as it would remain opened as long as a wearer is exhaling which would enable most if not all of the volume including 60-73% of gas exhaled by a wearer to pass through valve 12 of Simpson et al..

As to claim 79, since the mask body (1,2) of Simpson et al. is angled downwardly when positioned on wearer's face, the valve (12) on mask body (1,2) of Simpson et al. is positioned substantially opposite a wearer's mouth (fig.1). The valve flap (15) of Simpson et al. is mounted on the valve seat (fig.2) in cantilever fashion.

As to claim 80, the shape of the orifice (16) of Simpson et al. does not wholly correspond to the shape of the seal surface inasmuch as the seal surface surrounds the orifice.

Claim 81 is substantially equivalent in scope to claim 66 and is included in Simpson et al. as modified by Soderberg and Cover for the reasons set forth above with respect

to claim 66. Simpson et al. (page 1, lines 116-123) disclose a cup shaped mask body having a filtration layer and at least one shaping layer as well as an exhalation valve (fig.1) which is positioned on the mask body substantially opposite to a wearer's mouth when the mask is being worn.

As to claim 82, the shape of the orifice (16) of Simpson et al. does not wholly correspond to the shape of the seal surface inasmuch as the seal surface is rectangularly shaped and encircles the oval or round orifice (16).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Aaron J. Lewis

AARON J. LEWIS

Primary Examiner
Art Unit 3743

Aaron J. Lewis
March 09, 2006